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EXAMINER

HUYNH, PHUONG N

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/616,843	NASH ET AL.
	Examiner Phuong Huynh	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 February 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 14-24 and 27-32 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 14-24, and 27-32 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23&24.      6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 17-24, and 27-32 are pending.
2. The following new grounds of objection and rejections are necessitated by the amendment filed 2/6/03.
3. Claims 17 and 18 are objected to because said claims depend on cancel claim 11.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 14-24, and 27-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for (1) a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogen in the rumen or intestinal tracts of animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of immunogen to multiply, said protein-wasting immunogen is a P antigen from *P. anaerobius* or CS antigen from *C. Sticklandii*, or CA antigen from *C aminophilum* said method comprising:
  - A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P. anaerobius*, or CS antigen from *C. Sticklandii*, or CA antigen from *C aminophilum*
  - B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P. anaerobius* or CS antigen from *C. Sticklandii*, or CA antigen from *C aminophilum*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
  - C. Harvesting the eggs laid by the birds;
  - D. Separating the entire contents of said harvested eggs from the eggshells;
  - E. Drying said separated entire contents of said harvested eggs;
  - F. Distributing said dried entire contents of said harvested eggs substantially uniformly in animal feed or water to provide antibody-containing animal feed or water; and

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G. Supplying the resulting dried entire contents of said harvested and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens, in the intestinal tracts of the animals thereby promoting the growth of the animals

(2) the said method further comprises providing a dry feed carrier material, drying said entire contents of said harvested eggs by coating the carrier material with said entire contents of said harvested eggs, distributing said carrier material coated with said entire contents of said harvested eggs and animal feed or water to inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

(3) A method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogen in the rumen or intestinal tracts of animals by inhibiting the ability of the immunogen to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is a P antigen from *P. anaerobius* or CS antigen from *C. Sticklandii*, or CA antigen from *C aminophilium* said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P. anaerobius*, or CS antigen from *C. Sticklandii*, or CA antigen from *C aminophilium*

B. Allowing a period of time sufficient to permit the production in the birds and eggs laid by the birds of antibody in the eggs to P antigen from *P. anaerobius* or CS antigen from *C. Sticklandii*, or CA antigen from *C aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the eggshells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Distributing said carrier material coated with the entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting dry feed carrier material coated with the entire contents of said harvested and animal feed or water to food animals whereby the IgY immunoglobulins bind to the protein-wasting immunogens, in the intestinal tracts of the animals thereby promoting the growth of the animals, **does not reasonably provide enablement for** (1) a method as set forth in claims 17-24, and 27-32 wherein the "binding increased by the IgM and

IgA immunoglobulins to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a method of promoting the growth of the food animal by inoculating female bird with the specific immunogen such as P antigen from *P. anaerobius*, CS antigen from *C. Sticklandii*, CA antigen from *C. aminophilum*, harvesting the eggs, spray drying and pasteurizing whole powdered egg that contains egg antibody IgY from yolk, IgM and IgA from albumin, mixing said whole powdered egg in water supply, or a carrier such as pelleted soybean hulls and supplying said pelleted soybean hulls coated with the whole powdered egg containing the specific antibody to farm animal to inhibit the adherence of the specific immunogen in the intestinal tracts of the animal to promote the growth of the animals.

The specification does not teach the method mentioned above wherein the binding of IgY immunoglobulins to the protein-wasting immunogens being increased by the IgM and IgA immunoglobulins. There is no showing in the specification that the increased binding of IgY to protein-wasting immunogens being increased by the IgM and IgA. There is no guidance as how to determine the binding of IgY to the protein-wasting immunogens being increased by the IgM and IgA. There is no recognition in the art that egg IgM and IgA can increase the binding affinity of IgY binding to protein-wasting immunogens. *In re wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention. For these reasons, the specification as

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filed fails to enable one skill in the art to practice the invention without undue amount of experimentation. See page 1338, footnote 7 of *Ex parte Aggarwal*, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

6. Claims 14-24, and 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of a method as set forth in claims 17-24, and 27-32 wherein the "binding of IgY immunoglobulins to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals".

The specification discloses only a method of promoting the growth of the food animal by inoculating female bird with the specific immunogen such as P antigen from *P. anaerobius*, CS antigen from *C. Sticklandii*, CA antigen from *C. aminophilum*, harvesting the eggs, spray drying and pasteurizing whole powdered egg that contains egg antibody IgY from yolk, IgM and IgA from albumin, mixing said whole powdered egg in water supply, or a carrier such as pelleted soybean hulls and supplying said pelleted soybean hulls coated with the whole powdered egg containing the specific antibody to farm animal to inhibit the adherence of the specific immunogen in the intestinal tracts of the animal to promote the growth of the animals.

Other the specific methods method mentioned above, there is insufficient written description about the "binding of IgY immunoglobulins to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals" in the claimed methods.

Given the lack of a disclosure on the "binding of IgY immunoglobulins to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins to inhibit adherence of the protein-wasting immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals" in the claimed methods, Applicant was not in possession of the claimed limitations. Since the specification discloses only three protein-wasting immunogens such as such as P antigen from anaerobius, CS antigen from *C. Sticklandii*, CA antigen from *C.*

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aminophilum, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. Claims 14-16, 24, and 27-32 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The recitation of "binding of IgY immunoglobulins to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins" in claim 14 part G, claim 15 part G, claim 16 part G, claim 27 part H, claim 29 part H, claim 31 part H, of the amendment filed 2/6/03 represents a departure from the specification and the claims as originally filed. The specification discloses on page 10 line only that "the unique IgY types immunoglobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies". Applicants have not point out the support for said phrase comes from.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat No 5,585,098 (Dec 1996, PTO 1449) and US Pat No 5,741,489 (April 1998, PTO 892).

The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea (dietary protein wasting caused by diarrhea due to the presence of *E coli*) in livestock by inoculating an egg laying female birds such as the hen against a selected immunogen such as bacterium *E coli* (See column 5, lines 29-30, in particular), after a period of time such as a few weeks after the inoculation, the reference hen becomes sensitive to the reference immunized immunogen and produces the specific antibody to the immunized immunogen in the yolk and the albumin of the eggs (See column 5, lines 47-60, column 6, 10-18, in particular). The reference method includes collecting the egg laid by the hen (See column 6, line 1, in particular), separating the antibody against the inoculated immunogen from the yolk or albumin or both which is the entire content of the egg (See column 6, lines 19-20, in particular), drying the separated egg antibody by the process such as spray drying or lyophilizing to form powder product (See column 6, line 24-25, in particular), distributing the resulting dried egg antibody product as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal (See column 9, line 42-46, column 10, line 30, column 5 lines 29 bridging column 6, lines 1-49, column 9, lines 43-57, column 10, line 29-31, in particular). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The claimed invention in claim 14 differs from the teaching of the reference only that the method wherein the protein-wasting immunogen is P antigen from *P anaerobius* and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins from yolk of the eggs and IgM and IgA immunoglobulins from the albumin of the eggs bind to said protein-wasting immunogens in the intestinal tracts of the animals thereby promoting the growth of the animals.

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The claimed invention in claim 15 differs from the teaching of the reference only that the method wherein the protein-wasting immunogen is CS antigen from *C. sticklandii* and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins from yolk of the eggs and IgM and IgA immunoglobulins from the albumin of the eggs bind to said protein-wasting immunogens in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claim 16 differs from the teaching of the reference only that the method wherein the protein-wasting immunogen is CA antigen from *C. aminophilum* and that the method comprises distributing the dried entire contents of the harvested eggs uniformly in animal feed or water, supplying the resulting dried entire contents of said harvested eggs and animal feed or water to food animals whereby the IgY immunoglobulins from yolk of the eggs and IgM and IgA immunoglobulins from the albumin of the eggs bind to said protein-wasting immunogens in the intestinal tracts of the animals thereby promoting the growth of the animals.

Krause *et al* teach *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion and the growth of livestock (See entire document). Krause *et al* further teach adding antibiotic such as monensin as a ruminant feed additive decreases the number of *P. anaerobius* and *C. sticklandii* but not the number of *C. aminophilum* in livestock.

The '098 patent teaches that the yolk contains only IgY, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular).

The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '489 patent further teaches that egg antibodies are effective in decreasing the adhesion of enterotoxigenic *E. coli* onto enterocytes and protects from bacterial infection, in turn, increases feed conversion and body weight gain in mammals such as piglets and calves (See column 2, lines 49-61, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to substitute the immunogen such as the *E. coli* as taught by the '895 patent for the immunogens that are responsible for the protein wasting such as *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* as taught by Krause *et al* for

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a method of promoting the growth of food animal such as livestock by inoculating female birds in or about to reach their egg laying age with the protein wasting immunogen such as *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* as taught by Krause *et al*, harvesting the eggs laid by the birds after a period of time sufficient to permit the production of antibody in the bird and eggs laid by the birds wherein the IgY is located in the yolk while the IgM and IgA are located in the albumin or egg white as taught by the '098 patent, spray dried the whole egg preparation containing the egg antibodies as taught by the '489 patent and supplying the resulting dried entire contents of said harvested eggs as an additive to food for animal or as a solution such as milk to livestock to prevent adherence of the targeted immunogen in the intestinal tract of the animal as taught by the '895 patent, the '489 patent, Krause *et al* and the '089 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because Krause *et al* teach *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion and the growth of livestock (See entire document). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '098 patent teaches that the yolk contains only IgY, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular).

Applicants' arguments filed 2/6/03 have been fully considered but are not found persuasive.

Applicants' position is that (1) claims have been amended. (2) Tokoro et al ('895 patent) does not teach the use of albumin IgM and IgA in conjunction with the yolk IgY to inhibit

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adherence targeted immunogens in the intestinal tract of an animal. (3) There is no motivating directions in these references that would impel one skilled in the art to do the claimed method.

However, the '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '098 patent teaches that the yolk contains only IgY, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). Krause *et al* teach *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are the responsible for nutrition depletion and the growth of livestock (See entire document). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '489 patent also teaches that egg antibodies are effective in decreasing the adhesion of enterotoxigenic E coli onto enterocytes and protects from bacterial infection, in turn, increases feed conversion and body weight gain in mammals such as piglets and calves (See column 2, liens 49-61, in particular).

11. Claims 17-24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No. 5,080,895 (of record, Jan 1992; PTO 1449) in view of Krause *et al* (of record, Appl Environ Microbiol 62(3): 815-21; 1996, PTO 892), US Pat No 5,585,098 (Dec 1996, PTO 1449) and US Pat No 5,741,489 (April 1998, PTO 892) as applied to claims 14-16 above and further in view of US Pat 6,086,878 (of record, Jul 2000, PTO 892) and US Pat No. 4,166,867 (of record, Sept 1979, PTO 892).

The teachings of the '895 patent, Krause *et al*, the '098 patent and the '489 patent have been discussed *supra*.

The claimed invention in claims 17, 19, 21, 23, 27, 29 and 31 differs from the combined teachings of the references only that the method includes: providing a dry feed carrier material, drying the entire contents of the harvested eggs by coating the carrier material with said entire contents of the harvested eggs, distributing said carrier material coated with said entire contents

of the harvested eggs in animal feed or water and supplying the carrier material coated with said entire contents of the harvested eggs and animal feed or water to substantially prevent adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

The claimed invention in claims 18, 20, 22, 24, 28, 30 and 32 differs from the combined teachings of the references only that the method wherein the dry feed carrier material is selected from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

The '878 patent teaches hyperimmunized spray-dried egg powder can be mixed with food animal feed rations or sprayed to coat the directly onto food pellets to maintaining antibody titers sufficient to increase muscle protein and reduce fat in subject animal (See column 9, lines 37-46); the reference dried egg powder can be used in drinks, protein supplement (See column 9, lines 47-8, in particular). The '878 patent further teaches there is no need to separate the yolk form the albumin, except to achieve higher concentration of antibody (See column 9, line 62-65, in particular).

The '867 patent teaches a method of making a high performance palatable horse feed comprising soybean hulls, rice hulls cottonseed hulls which provide the fibrous material and cereal grain such as corn and distilled dried grains provide the carbonaceous materials along with nutritional supplement (See column 3, lines 24-26, column 3, lines 10-18, claims of '867, in particular) while beet pulp provides high energy values (See column 2, line 12-13, in particular). The '867 patent teaches soybean hulls, rice hulls and cottonseed hulls provide the fibrous material as animal feed in order to provide adequate structural strength or integrity to the final feed pellets and also to effect stool normality (See column 3, lines 14-16, in particular).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to coat any of the animal feed such as soybean hulls, rice hulls cottonseed hulls, cereal grain such as corn and distilled dried grains as taught by the '867 patent using the hyperimmunized spray-dried whole egg powder containing IgA and IgM in the albumin and IgY in the yolk as taught by the '878 patent, the '098 patent and the '489 patent immunized with the protein-wasting immunogen such as *Peptostreptococcus anaerobius*, *Clostridium sticklandii*, and *Clostridium aminophilum* as taught by Krause *et al* or the E coli as taught by the '895 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '867 patent teaches the carrier material such as soybean hulls, rice hulls and cottonseed hulls provide the fibrous material and provide adequate structural strength or integrity to the final feed pellets to effect stool normality (See column 3, lines 14-16, in particular). The '878 patent teaches hyperimmunized spray-dried egg powder is useful for mixing with any animal feed or sprayed directly to coat the food pellets to maintaining antibody titers (See column 9, lines 37-46). Krause *et al* teach immunogen such as *Peptostreptococcus anaerobius*, *Clostridium sticklandii*, and *Clostridium aminophilum* are responsible for nutrition depletion and the growth of livestock (See entire document) in livestock. The '895 patent teaches a method of promoting the growth of food animals by preventing diarrhea in livestock by adding bird antibody (IgY) against any desired immunogen of interest as a feed additive since the method of making bird antibody to any immunogen (bacteria) of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27).

The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '098 patent teaches that the yolk contains only IgY, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). The '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg (the entire content) as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular).

Applicants' arguments filed 2/6/03 have been fully considered but are not found persuasive.

Applicants' position is that (1) Adalsteinsson *et al* ('878 patent) does not teach coating a dry feed carrier with the entire contents of eggs separated from shells to dry the entire contents of the eggs. (2) Betz *et al* (the '867 patent) does not teach coating a dry feed carrier with the entire contents of eggs separated from shells to dry the entire contents of the eggs with soybean hulls, rice hulls or cotton hulls. The hulls are not used to dry any feed materials.

However, the '489 patent teaches that antibodies are more resistant to degradation by gastric acidity when they are contained in the spray dried whole egg as compared to purified antibody antibodies such as IgY from the yolk (See column 2, lines 36-39, in particular). The '098 patent teaches that the yolk contains only IgY, while IgM and IgA antibodies are found only in the white which is the albumin (See column 5, lines 54-57, in particular). Krause *et al* teach *Peptostreptococcus anaerobius*, *Closteridium sticklandii*, and *Clostridium aminophilum* are the culprit that responsible for nutrition depletion and the growth of livestock (See entire document). The '895 patent teaches the method of making bird antibody to any bacterial of interest is particularly advantageous due the fact that the procedure is simple, efficient and inexpensive (See column 9, line 43-47; column 3, line 19-27) and the bird antibody against the immunogen of interest as a food additive is effective for a method of preventing the immunogen from adhering to the rumen or intestinal tracts of livestock (food animal), which inherently promotes the growth of livestock by decreasing diarrhea such as waste of dietary protein caused by the presence of protein-wasting immunogen (See abstract, and claims of '895, in particular). The '489 patent also teaches that egg antibodies are effective in decreasing the adhesion of enterotoxigenic E coli onto enterocytes and protects from bacterial infection, in turn, increases feed conversion and body weight gain in mammals such as piglets and calves (See column 2, liens 49-61, in particular).

12. No claim is allowed.
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
  
15. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.  
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April 21, 2003

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